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**MAY 14 2008**

Serial No.: 10/757,159  
Examiner: Laura C. Schell  
Group Art Unit: 3767

### STATUS OF CLAIMS

Claims 11-20, 22, and 23 are presently pending and under examination. Applicant has amended claims 11 and 18 and added new claims 26-38. Support for the amendment to claims 11 and 18 is found in the specification and claims as originally filed and specifically, on page 5, lines 12 to 20 and Figures 1, 2, 3A, 3B, 3C, 3D, 3E, 5, 6A and 6B and their accompanying text. Applicant has amended the specification on pages 5 and 6 to correct two errors of a typographical nature. Support for the correction to the specification is provided in Figure 3B, which shows the screw feature as amended. Support for the new claims is provided in the original claims and specification and drawings as filed and specifically, Figures 1, 2, 3A, 3B, 3C, 3D, 3E, 5, 6A and 6B and their accompanying text. Applicant submits that no new matter has been added.

### REMARKS

#### Rejection Under 35 U.S.C. §102(b) – Schwartz-Feldman

Claims 11 and 17 are rejected as being anticipated by Schwartz-Feldman (U.S. Pat. No. 5,501,371).

In response, Applicant respectfully traverses the rejection over Schwartz-Feldman. Applicant submits that the invention is not anticipated by the disclosures of Schwartz-Feldman. As amended, claim 11, from which rejected 17 depends, is directed to the following:

A driving system for use with an injector system, the injector system comprising: a housing defining a lumen and having an output end and a driving system connection end, the lumen comprising a proximal portion and a distal portion and the inner diameter of the proximal portion being substantially larger than the inner diameter of the distal portion; a needle assembly coupled to the output end of the housing for coupling to a needle; and a mixing member extending through the lumen from the driving system connection end to at least the output end, the mixing member being rotatable within the lumen in both the proximal portion and the distal portion; and

the driving system comprises:

a drive mechanism;

an actuator coupled to the drive mechanism to actuate the drive mechanism; and a rotatable interfacing member coupled to the drive mechanism for coupling with the mixing member to rotate the mixing member when the interfacing member is driven by the drive mechanism, wherein the mixing member is rotatable in the needle assembly and the lumen.

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The Schwartz-Feldman reference fails as an anticipatory reference because it fails to teach all of the claimed features of amended claim 11. For a reference to anticipate a claim it must disclose each and every element of the claim. *See* MPEP 2131 and cases cited therein, especially *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198 USPQ 344, 346 (Fed. Cir. 1978).

For example, Schwartz-Feldman does not teach "a lumen comprising a proximal portion and a distal portion and the inner diameter of the proximal portion being substantially larger than the inner diameter of the distal portion." Schwartz-Feldman also does not teach "a mixing member being rotatable within the lumen in both the proximal portion and the distal portion." Rather, as illustrated by Figures 1, 2, 7, 8, and 9, the device of Hicks et al. is a "mixing syringe 20...[that] comprises a storage area 22...[which] further comprises a *cylindrical* syringe body 28." (Schwartz-Feldman et al., col. 3, lines 5-9)(emphasis added).

In addition to these missing claim features, Applicant maintains its previous position that Schwartz-Feldman also does not teach a mixing member that extends into the needle assembly and even if it were assumed that such were the case, it does not teach a mixing member which is rotatable in the needle assembly. End portion 140a, which the Examiner cites as purportedly showing that the mixing member extends into the needle assembly, is not a part of the mixing means of Schwartz-Feldman's device, but rather, is a member that is attached to the casing ("mixing cylinder" 102) that holds the mixing means. The "end portion 140a" referred to by the Examiner refers to one of four "planar flanges 140a, b, c, and d" that is distal to the mixing mechanism taught in Schwartz-Feldman. ("Distal point 130 includes an annular beveled valve surface 138 and a plurality of *planar flanges 140a, b, c, and d* radially positioned about the center axis of cylindrical body 120. Planar flanges 140a, b, c, and d include an upper positioning tab 142a, b, c, and d and a lower stop tab 144a, b, c, and d;" col. 3, lines 62-67)(see col. 4, lines 57-60, which explains how the positioning tabs on the planar flanges help to affix a valve 138 that prevents inadvertent leakage of materials during the mixing action).

This is illustrated in Figures 1 and 7-9 of Schwartz-Feldman which show that mixing would occur in the "cylindrical body 120" of the mixer cylinder 102 and not in the distal point 130. As shown in these figures in Schwartz-Feldman, the mixing means 26 is proximal to, and does not extend into, the tapered tip 84 (which the Examiner indicates reads upon the claimed

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"needle assembly"). That is, mixing occurs by a "mixing means 26 compris[ing] a paddle mixer 100 and a paddle mixer cylinder 102. Paddle mixer includes a circular planar head 104, a stem 106, and a plurality of paddle blades 108a, b, and c. Circular planar head 104 includes a plurality of notches 110a, b, c, and d for spatially coinciding with, and mechanically engaging the plunger inner ribs 66a, b, c, and d respectively." (Schwartz-Feldman, col. 3, lines 36-49).

The actual mixing that occurs in the operation of the device is illustrated in sequential steps in Figures 7-10. "The mixing process is initiated by partially retracting paddle blades 108a, b, and c through the process of rotating plunger 50 as depicted in FIG. 7. Plunger inner ribs 66a, b, c, and d are mechanically engaged to notches 110a, b, and c, transmitting the twisting motion placed on plunger 50 to paddle mixer 100...Continued rotation of plunger 50 results in a *spinning motion of mixing means 26 about the long axis of paddle mixer 100*. (col. 4, lines 33-42). The spinning motion does not further extend distally from the distal tip of the paddle mixer 100.

As illustrated above, since Schwartz-Feldman is lacking features of the claimed invention, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection over Schwartz-Feldman. Claim 17 is dependent directly on claim 11, and the rejection of that claim fails at least because of the fundamental defect discussed above.

Rejection Under 35 U.S.C. §103(a) – Schwartz-Feldman in view of Critchlow

Claims 12-16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Schwartz-Feldman (U.S. Pat. No. 5,501,371) in view of Critchlow et al. (US 2003/0171712). The Examiner takes the position that Schwartz-Feldman discloses the invention of claim 12-16.

In response, Applicant respectfully traverses the rejection and its accompanying remarks. Claims 12-16 are dependent directly on claim 11, discussed above, and the rejection of that claim fails at least because of the fundamental defect discussed above. Applicant asserts that given the deficiencies noted above with respect to Schwartz-Feldman, which is the primary reference, the combination of the disclosures of Schwartz-Feldman with the secondary reference, Critchlow et al., fails to establish a *prima facie* case of obviousness.

Applicant states that the Examiner has not met her burden of establishing a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, three basic criteria must be

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met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claimed features. MPEP § 2142-2143; *see In re Jones*, 958 F.2d 347, 351, 21 U.S.P.Q.2d 1941, 1943-44 (Fed. Cir. 1992); *In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q. 1596, 1598-99 (Fed. Cir. 1988). In addition, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaack*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicant states that the rejection fails at least because the prior art references, in combination, fail to teach or suggest all the claim limitations. Specifically, Critchlow et al. fails to teach the claimed features which are missing in Schwartz-Feldman, discussed *supra* with respect to claim 11, upon which rejected claims 12-16 depend. Critchlow et al. teaches a pressurized fluid injector that includes a drive mechanism to pressurize the fluid (Critchlow et al., paragraph [0009]). Critchlow et al. does not teach "a lumen comprising a proximal portion and a distal portion and the inner diameter of the proximal portion being substantially larger than the inner diameter of the distal portion." Critchlow et al. does not teach "a mixing member being rotatable within the lumen in both the proximal portion and the distal portion." Critchlow et al. does not teach a mixing member that extends into the needle assembly.

Applicant states that dependent claims 12-16 contain additional features which further distinguish them from the cited prior art. In light of the above, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of the claims as unpatentable over Schwartz-Feldman in view of Critchlow et al.

#### Rejection Under 35 U.S.C. §102(b) - Hicks

Claims 18-20, 22, and 23 are rejected under 35 U.S.C. § 102(b) as being anticipated by Hicks (U.S. Patent No. 2,825,134).

In the Office Action, the Examiner takes the position that Hicks discloses the claimed coupling system for use with a tube of a syringe, comprising: a housing for coupling to the tube of the syringe; a drive mechanism disposed within the housing; a mixing member for coupling to the drive mechanism, the mixing member for extending into the tube of the syringe and being

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rotatable within the tube of the syringe to mix and deliver an injectable from the tube of the syringe; and an actuator coupled to the drive mechanism to actuate the drive mechanism and thereby cause rotation of the mixing member.

In response, Applicant respectfully traverses the rejection over Hicks. Applicant submits that the invention of claim 18, as amended, is not anticipated by Hicks. As amended, claim 18, from which the remainder of the rejected claims depends, is directed to the following:

A coupling system for use with a tube of a syringe comprising a proximal portion and a distal portion and the inner diameter of the proximal portion being substantially larger than the inner diameter of the distal portion, wherein the coupling system comprises: a housing for coupling to the tube of the syringe; a drive mechanism disposed within the housing; a mixing member for coupling to the drive mechanism, the mixing member extending into the tube of the syringe and being rotatable within the tube of the syringe in both the proximal portion and the distal portion to mix and deliver an injectable from the tube of the syringe; and an actuator coupled to the drive mechanism to actuate the drive mechanism and thereby cause rotation of the mixing member.

For example, Hicks et al. does not teach "a tube of a syringe comprising a proximal portion and a distal portion and the inner diameter of the proximal portion being substantially larger than the inner diameter of the distal portion." Schwartz-Feldman also does not teach "a mixing member being rotatable within the tube of the syringe in both the proximal portion and the distal portion." Thus, Hicks does not teach the various features of independent claim 18. For a reference to anticipate a claim it must disclose each and every element of the claim. See MPEP 2131 and cases cited therein, *especially Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198 USPQ 344, 346 (Fed. Cir. 1978).

Since Hicks et al. fails as an anticipatory reference, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection over Hicks. Claims 19, 20, 22, and 23 depend directly on claim 18 and contain additional distinguishing features. The rejection of those claims fails at least because of the fundamental defect discussed above with respect to independent claim 18.

### CONCLUSION

Applicants respectfully submit that all pending claims are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an

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interview would expedite the application at large, request is made that the Examiner telephone the undersigned attorney at (908) 518-7700, ext. 7 in order to resolve any outstanding issues.

#### FEES

The Office is authorized to charge any fees required, including the fee for a one-month extension of time to deposit account number 50-1047.

Respectfully submitted,

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